REMARKS

Claim 1, 3-9 and 11-18 are pending. Claims 1, 4, 9, 11, 12 and 16 are amended herein. Claims 17-18 are new. No new matter is added.

Issues in the pending office action:

- 112 ¶ 2 – alleged indefiniteness for omitted essential elements
- 112 ¶ 1 – alleged new matter/lack of written description
- 112 ¶ 1 – alleged lack of enablement

I. 112 ¶ 2

The office action indicates that the Applicant has not provided support for the omitted elements and that failed to otherwise rebut the Examiner's rejection. The office action refers to the rejection issued in the prior office action of 22 January 2007. The basis of this rejection was:

> Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: converting solid fuels. It is noted that converting is given in the preamble of claim 1 but no step is given describing this conversion, especially how it is to be accomplished. It is also unclear how the microorganisms of these claims relate to the conversion as no active step is given in which the microorganisms interact with the solid fuels.

In response, Applicant amended the claims to formally recite a positive step wherein the microorganism acted on the starting materials:

> d) combining the host microorganism with the solid fossil fuels or oil tars under conditions suitable for the conversion of the solid fossil fuels or oil tars into synthetic petroleum.

This step is still present in the instant claims. In the subsequent final office action of 11 December 2007, the Examiner withdrew the rejection issued 22 January 2007 in view of the above amendment:

> The rejection of claims 1, 3, and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for recitation of "converting of solid fuels, including coal . . . by distillation of coal . . ." is withdrawn. Applicant has overcome this rejection through amendment to the claims.

The nature of the instant rejection is thus unclear. Applicant had presumed it was the alternative basis expressed in the final office action of 11 December 2007:

> Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: what conditions are suitable for conversion of the solid fuels or oil tars into synthetic petroleum. A search of the specification by Examiner did not reveal where "conditions suitable for conversion" are given.

In reply, Applicant has carefully pointed out that the above basis of rejection is not properly framed as an indefiniteness issue. Response filed 27 March 2008, section II., A. The Examiner's rejection is not grounded in lack of clarity but is rather an aspect of the Examiner's (equally improper) 112 ¶ 1 position.

II. 112 ¶ 1

A. Written Description/New Matter

Applicant has amended the claims to be directed to biosynthetic petroleum to further clarify the role of microorganisms in the claimed processes. Applicant reiterates section III., A. of the response filed 07 March 2008. The Examiner's contends a *prima facie* case is established and unrebutted. Applicant respectfully disagrees that a proper rejection is made and thus there is nothing to rebut.

B. Enablement

Applicant analyzes below, the enablement for independent claims 1 and 11. Claim 9 is comparable to claim 1 except that subtraction hybridization screening for orthologs is specifically claimed. Applicant thus contends that the analysis of claim 1 applies to claim 9.

1. Claim 1

Claim 1 is directed to a method of converting (i) solid fossil fuels, or (ii) oil tars obtained by distillation of coal, turf, grass, rubber, sapropel, sapropelites, slates, or wood, into biosynthetic petroleum, comprising the steps of:

a) isolating a starting microorganism capable of said conversion;

This step is what is commonly referred to as "bioprospecting." *See* "Bioprospecting: History and Background" The National Park Service, U.S. Dept. of the Interior, http://www.nature.nps.gov/benefitssharing/bphistory.cfm. The famous example of Taq Polymerase is discussed as an example. Examples of the successful practice of this step may be found in the Kurashkov, et al. cited by the Examiner and the specific species of microorganisms identified in claim 3. The art also demonstrates enablement of assays for whether a microorganism is capable of converting solid fossil fuels to biosynthetic petroleum. *See* Kurashkov, et al.; Martin S. Cohen and Peter D. Gabriele, Degradation of Coal by the Fungi Polyporus versicolor and Poria monticola, *Appl Environ Microbiol.* 1982 July; 44(1): 23-27 ("Cohen"). The Examiner appears to concur in as much as this aspect of the claimed process does not appear to be specifically challenged. The Examiner indirectly touches on step a) in discussing the Zaldivar reference. The Examiner states:

> The lack of a microorganism is a problem for any fuel production by microrganisms, including the claimed invention.

Office action, issued 17 June 2008, page 7. This is quite true. The issue is whether microorganisms capable of the claimed conversions are ascertainable. Applicant respectfully submits the example microorganisms recited in claim 3 and identified by Kurashkov, et al. and Cohen demonstrate the answer is yes.

b) isolating from the starting microorganism the genes responsible for the conversion ability;

The next step in the claimed process involves cloning of the genes responsible for the identified microorganisms' ability to convert solid fossil fuels to biosynthetic petroleum. The specification expressly identifies a subtraction hybridization/screening approach for isolating the genes. *See* [0008]-[0011] of the published application. Expression screening and other standard molecular biology techniques for screening and isolating these genes were well established in the art. *See, e.g.*, King RW, Lustig KD, Stukenberg PT, McGarry TJ, Kirschner MW. Expression cloning in the test tube. Science. 1997 Aug 15;277(5328):973-4. The Examiner has no doubt in the past lamented the omnibus, mega-disclosures reproducing large portions of the contents of Sambrook and Current Protocols in Molecular Biology. The courts have ruled consistently over thirty years that the pointless reproduction of how to perform well known methods, *e.g.*, how to do SDS-PAGE, is both unnecessary and undesirable. See, e.g., *In re Myers*, 410 F.2d 420, 424 (C.C.P.A. 1969) ("A specification is directed to those skilled in the art and need not teach or point out in detail that which is well-known in the art."); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463 (Fed. Cir. 1984) ("The question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art."); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] **patent need not teach, and preferably omits, what is well known in the art**.") (emphasis added); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987) (quoting *Hybritech*); *Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006) (quoting *Spectra-Physics*). Having isolated microorganisms with the desired biological activities, the process step of cloning the genes behind that activity represents the application of well established molecular biology techniques.

The Examiner's rejection of 11 December 2007 applies the further rational summarized by the following Examiner quotation:

> "In the above cases, there is much work to be done with respect to describing both the genetic systems and the enzymes involved. Even more challenging will be answering questions such as . . .
> how the different approaches to alkane metabolism evolve and how are they related, and how well-characterized and novel metabolic pathways can be applied in fine-chemical synthesis" (see 2nd paragraph of 2nd column on p. 506).

Page 11. It is unclear to Applicant what the relevancy of the above is to the capacity of the state of the art to enable doing the work to answer the above questions. Further, the delineation of, *e.g.*, how alkane biosynthetic systems evolved, is not relevant to the issue of whether the genes responsible for converting solid fossil fuels to biosynthetic petroleum may be isolated from the microorganisms identified in step a). Indeed, the delineation of the genes for the biosynthetic system described in the cited Hamme, et al. reference clearly demonstrates the state of the art enabled the instantly claimed process step b).

c) transfecting the genes into a host microorganism, and

The Examiner's issues with this step of the claimed process appear to break down into two discrete subjects. First, the Examiner questions the ability in the state of the art to generate transgenic hosts generally:

> The teachings of Zaldivar et al. as cited in the previous Office Action do not support Applicant contention that transfecting a gene for subsequent expression is routine as a cell/microorganism is complex and the consequences of genetic changes are difficult to predict.

Office action issued 17 June 2008, page 12. Applicant refers the Examiner to the standard protocol references which Applicant believes are readily available in the USPTO reference collections:

- Current Protocols in Molecular Biology UNIT 13.4 Yeast Cloning Vectors and Genes; DOI: 10.1002/0471142727.mb1304s21 Online Posting Date: May, 2001 Print Publication Date: January, 1993

- Current Protocols in Molecular Biology UNIT 1.8 Introduction of Plasmid DNA into Cells; DOI: 10.1002/0471142727.mb0108s37 Online Posting Date: May, 2001 Print Publication Date: January, 1997

Applicant contends it is unnecessary to submit copies of such basic protocols, or other texts documenting the state of the art of which the Examiner is already well aware. If the Examiner does not have adequate resources or sufficient personal knowledge to determine the state of the art, Applicant will be happy to provide relevant portions of the above or comparable references upon request. The Examiner implicitly concedes that the above is well within the skill in the art with the second element of the Examiner's position:

> Even if transfecting a gene is somewhat routine, transfecting a suite of genes which must subsequently act in proper concert is not and this is the claimed invention, which is to "genes" and not a "gene" for producing mixtures of substances, not just one substance.

Office action issued 17 June 2008, page 12. While the Examiner is not particularly detailed on this point, the issue the Examiner raises appears to be the state of the art of synthetic biology as it relates to the claimed process step. *See, e.g.*, Steven A. Benner & A. Michael Sismour, "Synthetic biology," *Nature Reviews Genetics* 6, 533-543 (July 2005) (doi:10.1038/nrg1637). The state of the art of synthetic biology as it applies to microorganism based biofuels was adequately developed as of the priority date of the instant application to enable one of ordinary skill in the art to transfect multiple genes to work together to produce complex biosynthetic pathways. *See, e.g.*, Vincent J. J. Martin, Douglas J. Pitera, Sydnor T. Withers, Jack D. Newman, and Jay D. Keasling, "Engineering a mevalonate pathway in Escherichia coli for production of terpenoids," *Nature Biotechnology*, 1 July 2003; Kalscheuer R, Stölting T, Steinbüchel A. Microdiesel: Escherichia coli engineered for fuel production. Microbiology. 2006 Sep;152(Pt 9):2529-36; WO2007/0136762 (Examples 2-8). These examples of synthetic biology applied to microorganism based terpenoid and biofuel production demonstrate the state of the art was

both enabling for one of ordinary skill in the art and was fully enabled to execute step c) as claimed.

d) combining the host microorganism with the solid fossil fuels or oil tars under conditions suitable for the conversion of the solid fossil fuels or oil tars into biosynthetic petroleum.

The foregoing identified references also demonstrate the advanced state of the art with regard to optimizing microbiological culturing conditions. This general state of the art has also been successfully applied to define conditions suitable for the conversion of the solid fossil fuels into biosynthetic petroleum. *See* Kurashkov, et al.; Martin S. Cohen and Peter D. Gabriele, Degradation of Coal by the Fungi Polyporus versicolor and Poria monticola, *Appl Environ Microbiol*. 1982 July; 44(1): 23-27 ("Cohen"). Each specific embodiment of transgenic host and transgene(s) will require some experimental work to define optimum culture conditions. This does not represent undue experimentation.

2. Claim 11

Claim 11 is directed to A method of converting carbon, hydrogen and oxygen into biosynthetic coal or synthetic petroleum, comprising the steps of:

(a) isolating a starting microorganism capable of said conversion;

(b) isolating from the starting microorganism the genes responsible for the conversion ability;

(c) transfecting the genes into a host microorganism; and

(d) combining the host microorganism with the carbon, hydrogen and oxygen under conditions suitable for the conversion of the carbon, hydrogen and oxygen into biosynthetic coal or biosynthetic petroleum.

With regard to claim 11, the enabling state of the art for the claimed method is established by analogy to the evidence and explanation for claim 1. *See above*, Vincent J. J. Martin, Douglas J. Pitera, Sydnor T. Withers, Jack D. Newman, and Jay D. Keasling,

"Engineering a mevalonate pathway in Escherichia coli for production of terpenoids," *Nature Biotechnology*, 1 July 2003; Kalscheuer R, Stölting T, Steinbüchel A. Microdiesel: Escherichia coli engineered for fuel production. Microbiology. 2006 Sep;152(Pt 9):2529-36; WO2007/0136762 (Examples 2-8).

In addition, Applicant cites more evidence for claim 11, steps a) and b). *See*, Dennis M, Kolattukudy PE. A cobalt-porphyrin enzyme converts a fatty aldehyde to a hydrocarbon and CO. Proc Natl Acad Sci U S A. 1992 Jun 15;89(12):5306-10; http://www.biofuelsdatabase.org/map/alkane-decarbonylation_map.shtml ; http://www.biofuelsdatabase.org/map/alkane_map.shtml . These references demonstrate the enabling state of the art for both identification of microorganisms capable of producing biosynthetic petroleum and identification of the genes responsible for this activity.

For claim 11, steps c) and d), the success of LS9 in making biosynthetic petroleum is a direct example of applying synthetic biology to create transgenic hosts and determining conditions suitable for producing biosynthetic petroleum. *See*, Neil Savage, Building Better Biofuels, *Technology Review* (MIT), June 06, 2007 ("LS9-A"); Chris Ayres, Scientists find bugs that eat waste and excrete petrol, *The TimesOnline*, June 14, 2008; Next-generation biofuels: nearly identical to gasoline and diesel, *Plenty* May 21, 2008, http://www.plentymag.com/features/2008/05/strange_crude.php ("LS9-B"). LS9 was formed in 2005, after publication placed Applicant's invention in the public domain. *See* LS9-A. One aspect of LS9's biofuels program was "to use synthetic biology to develop microorganisms that produce biofuels." *Id.* As of the June 6, 2007 publication date of LS9-A, "LS9 microbes produce and excrete hydrocarbons that are useful as fuels. Now the company is working to customize the rate of production and the products themselves." It is logical to infer that LS9's experimentation did not begin the day the entity was created and that the biosynthetic petroleum producing transgenic hosts had not been reduced to practice the day before June 6, 2007. It is thus likely that the period of time required to derive the LS9 microorganisms was significantly less than two years. This demonstrates that the process the Examiner characterizes as nonenabled, was successfully done in no more than two years time, starting soon after the instant application was published. At least by May of 2008, LS9 had optimized the biosynthetic petroleum composition to "about ten" alkanes species. *See* LS9-B. "The company's oil will have the molecular diversity necessary to

make a number of fuels and petroleum products but will be free of unwanted chemicals that can muck up engines." *Id.* In view of this success, LS9-A quotes Jim McMillan, principal biochemical engineer in the U.S. DOE National Renewable Energy Laboratory's Bioenergy Center, "I don't doubt that [making hydrocarbon fuel from microbes] can be done; the question is how quickly and at what cost." *Id.* The top U.S. government expert in this area thus confirms the general enablement of the claimed processes. *Id.* Applicant contends this is an example of the state of the art that the instant disclosure was thus within the capacity of one of ordinary skill in the art. What was lacking in the art was the invention itself, the conception of the invention. *Cf.* " 'We certainly have gone beyond what we think anybody else was even thinking of doing' in terms of producing hydrocarbons from microbes, says George Church, a geneticist at Harvard Medical School and one of LS9's two founders." *Id.*

3. Commercial Scale Production and Economic Competitiveness

The Examiner maintains that Applicant's specification contemplates an ultimate goal of commercial production and that the claims would read on commercial scale production. This mirrors the challenge facing all biofuels. *See, e.g.*, LS9-A ("LS9 now needs to prove that its technology is economical and can produce fuels on a large scale, says Jim McMillan, principal biochemical engineer in the National Renewable Energy Laboratory's Bioenergy Center."). As a matter of policy, the courts have very clearly defined enablement as not requiring this degree of reduction to practice. *See* Applicant's response filed 20 July 2007, page 11 (entire). The Examiner's approach to this issue is multifaceted. The most facially erroneous contention is:

> First, the claims do not exclude "commercially viable biofuel production" which the instant specification attempts to achieve (see p. 6 lines 5-8). Thus such production is relevant to the instant claims.

Office action, issued 17 June 2008, page 5. This is simply contrary to the law. *CFMT, Inc. v. YieldUP International Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003) ("Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and

use a perfected, commercially viable embodiment **absent a claim limitation to that effect**.") (emphasis added)

Next, the Examiner attempts to leverage the words "commercial production" in claim 16 to fit the claimed subject matter into an exception to the above law:

> As already noted above the claims do recite the limitation of "commercial production" and thus prior art which addresses commercial production is relevant to the instant claims.
>
> However, the instant claims are to the same production as addressed by Zaldivar et al. both generally and specifically, i.e., the "commercial production" of instant claim 16).

Office action, issued 17 June 2008, pages 6 and 7. In so doing, the Examiner tacitly concedes the above point of law on commercial enablement and attempts to shoehorn the instant claims into an exception. *CFMT, Inc. v. YieldUP International Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003) ("Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment **absent a claim limitation to that effect**.") (emphasis added). The Examiner's basis is exemplified by the following:

> These relevant teachings stand alone whether quoted or seen in context. Regardless the teachings of "industrial background" and "industrial purposes" of Zaldivar et al. are relevant and especially relevant to the "commercial production" of instant claim 16.

Office action, issued 17 June 2008, page 7. This is very clever and superficially effective, but the actual context of "commercial production" in claim 16 does not support application of the above exception. Applicant contends the rejection is substantively incorrect based on the complete context of the claim element: "before transfection, the genes are selectively altered, and following transfection with such selectively altered genes, the host microorganisms with

characteristics best suited to commercial production of biosynthetic coal or biosynthetic petroleum are selected." The process limitation is to a mutagenesis/screening step to identify "host microorganisms with characteristics best suited to commercial production." This is in line with the ultimate contemplated goal of commercial production expressed in the specification. A further process step of strain improvement, with the goal of commercial production in mind, is not a claim to commercial production of biosynthetic petroleum. The Examiner's sharp tactic demonstrates the lack of legitimate basis behind the instant rejection.

Finally, the Examiner advances the argument that the contents of the references cited are not specific to commercial/scale-up issues but also evidence a more fundamental level of non-enablement. Applicant has already provided a detailed analysis of the Examiner's references and how they do not support the Examiner's position. *See* Applicant responses filed 20 July 2007, Section IV.; 07 March 2008, section III., B. Applicant further contends the Examiner's evidence related to ethanol production is less probative of the enablement of the instant claims relative to the evidence supplied herein. Applicant's supplemental evidence herein shows the Examiner's contention on the state of the art is incorrect.

Conclusion

In view of the above, applicant believes the pending application is in condition for allowance. Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P03493US0 from which the undersigned is authorized to draw.

Dated: September 5, 2008

Respectfully submitted,

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